

(b) Affected ADs

None.

(c) Applicability

This AD applies to Honeywell International Inc. (Honeywell) TPE331-1, -2, -2UA, -3U, -3UW, -5, -5B, -6, -6A, -8, -10, -10AV, -10N, -10P, -10R, -10T, -10U, -10UA, -10UF, -10UR model turboprop and TSE331-3U turboshaft engines with hydraulic torque sensor gear assemblies, part numbers (P/Ns) 3101726-1, -2, or -3, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7210, Turbine Engine Reduction Gear.

(e) Unsafe Condition

This AD was prompted by recent reports of failures of the direct drive fuel control gears and bearings in the hydraulic torque sensor gear assembly, P/N 3101726-3. We are issuing this AD to prevent failure of the hydraulic torque sensor gear assembly, in-flight shutdown, and reduced control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Oil Filter Sampling and Analysis

(1) Obtain an initial engine oil filter sample of the affected engines within 150 hours time in service after the effective date of this AD. Guidance for obtaining oil filter samples can be found in Honeywell's engine training manuals; for example, see the TPE331 Line Maintenance Training Manual.

(2) Submit engine oil filter sample within 3 days of sampling to an ISO/IEC 17025-accredited laboratory capable of performing analysis using ASTM D5185, Standard Test Method for Multielement Determination of Used and Unused Lubricating Oils and Base Oils by Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES). A list of Honeywell-authorized laboratories capable of performing this analysis can be found in paragraph 1.D.(10) of Honeywell Service Information Letter (SIL) P331-97, Revision 11, dated July 23, 2008.

(3) Perform an oil filter analysis for wear metals and evaluate filter contents using paragraphs 1.D.(4) and (5) of Honeywell SIL P331-97, Revision 11, dated July 23, 2008. Guidelines for interpreting analysis results can be found in paragraph (8) of Honeywell SIL P331-97.

(4) For those engines where the oil filter analysis indicates the need for an inspection or resample, as specified in Figures 1, 2 or 3 of the Honeywell SIL P331-97, Revision 11, dated July 23, 2008, accomplish the following:

(i) If Figures 1, 2, or 3 indicate an inspection is required, within 5 days, inspect the torque sensor gear assembly using paragraph (g)(5) of this AD.

(ii) If Figures 1, 2, or 3 indicate a resample is required, perform a repeat oil filter sample and analysis, within 25 hours time in service from the previous sample, to evaluate for wear metals in accordance with paragraphs (g)(1), (2) and (3) of this AD.

(A) If the resample indicates a second resample or inspection is required, within 5 days, inspect the hydraulic torque sensor gear assembly using paragraph (g)(5) of this AD.

(B) Reserved.

(5) Inspect the hydraulic torque sensor gear assembly using the following steps:

(i) Remove bearings, P/Ns 358893-1, 3103035-1, 3103585-1 or 70100168-1, from the assembled spur gear and fuel control drive gearshaft and inspect or replace. Guidance for performing the inspection can be found in Section 70-00-00, Standard Practices of the applicable TPE331 engine maintenance manual. For example, see paragraph 5., "Bearing Inspection," on pages 11-12 of Honeywell Maintenance Manual 70-00-00, TPE331-10 (Report No. 72-00-27), dated February 29, 2000.

(ii) Visually inspect the gearshaft teeth for scoring, pitting, chipping, metal deposits or corner breakage. Visual defects on gear teeth are acceptable if defects cannot be felt using a 0.031 inch diameter stylus. No corner breakage is allowed.

(iii) For any hydraulic torque sensor gear assembly that fails the inspection required by paragraph (g)(5) of this AD, remove the affected hydraulic torque sensor gear assembly and, before further flight, replace with a part eligible for installation.

(6) Thereafter, repeat the steps identified in paragraphs (g)(1) through (5) of this AD every additional 150 hours time in service after last oil filter sampling.

(h) Hydraulic Torque Sensor Gear Assembly Overhaul

After the effective date of this AD, do not use the Honeywell Torque Sensor Gear Assembly Overhaul Manual with Illustrated Parts List, 72-00-17, Revision No. 9, dated, July 20, 1992, or earlier versions, to overhaul TPE331 or TSE331 hydraulic torque sensor gear assemblies, P/Ns 3101726-1, -2, or -3.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, FAA, Los Angeles ACO Branch, Compliance and Airworthiness Division, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the Los Angeles ACO Branch, send it to the attention of the person identified in paragraph (j)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

(1) For more information about this AD, contact Joseph Costa, Aerospace Engineer, FAA, Los Angeles ACO Branch, Compliance and Airworthiness Division, 3960 Paramount Blvd., Lakewood, CA 90712-4137; phone: 562-627-5246; fax: 562-627-5210; email: joseph.costa@faa.gov.

(2) For service information identified in this proposed AD, contact Honeywell

International Inc., 111 S 34th Street, Phoenix, AZ 85034-2802; phone: 800-601-3099; Internet: <https://myaerospace.honeywell.com/wps/portal>.

(3) You may view this service information at the FAA, Engine and Propeller Standards Branch, Policy and Innovation Division, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781-238-7125.

Issued in Burlington, Massachusetts, on September 7, 2017.

Robert J. Ganley,

Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2017-19314 Filed 9-12-17; 8:45 am]

BILLING CODE 4910-13-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1420

[CPSC Docket No. 2017-0032]

Amendment to Standard for All-Terrain Vehicles; Notice of Proposed Rulemaking

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Improvement Act of 2008 (CPSIA) required the Consumer Product Safety Commission (CPSC or the Commission) to publish, as a mandatory consumer product safety standard, the *American National Standard for Four-Wheel All-Terrain Vehicles Equipment Configuration, and Performance Requirements*, developed by the Specialty Vehicle Institute of America (ANSI/SVIA 1-2007). CPSC published that mandatory consumer product safety standard on November 14, 2008. ANSI/SVIA issued a 2017 edition of its standard in June 2017. In accordance with the CPSIA, CPSC proposes to amend the Commission's mandatory ATV standard to reference the 2017 edition of the ANSI/SVIA standard.

DATES: Submit comments by November 27, 2017.

ADDRESSES: Comments related to the proposed rule, identified by Docket No. CPSC-2017-0032, may be submitted electronically or in writing:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by email, except through www.regulations.gov. The Commission encourages you to submit electronic comments by using the

Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the docket number, CPSC-2017-0032, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT:

Caroleene Paul, Project Manager, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987-2225; email: cpaul@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The CPSIA directed the Commission to "publish in the **Federal Register** as a mandatory consumer product safety standard the American National Standard for Four Wheel All-Terrain Vehicles Equipment Configuration, and Performance Requirements developed by the Specialty Vehicle Institute of America (American National Standard ANSI/SVIA 1-2007)." 15 U.S.C. 2089(a)(1), as added by section 232 of the CPSIA. Accordingly, on November 14, 2008, CPSC published a final rule mandating ANSI/SVIA 1-2007 as a consumer product safety standard. 73 FR 67385. The final rule was codified at 16 CFR part 1420. The Commission has revised the mandatory standard once in accordance with the revision procedures set out in the CPSIA. On February 29, 2012, the Commission published a final rule that amended the Commission's ATV standard to reference the 2010 edition of the ANSI/SVIA standard. 77 FR 12197. On June 14, 2017, ANSI notified the Commission that the 2010 edition of the ANSI/SVIA standard had

been revised, and that the new standard, ANSI/SVIA 1-2017, was approved on June 8, 2017.

Section 42(b) of the CPSA provides that, if ANSI/SVIA 1-2007 is revised after the Commission has published a **Federal Register** notice mandating the standard as a consumer product safety standard, ANSI must notify the Commission of the revision, and the Commission has 120 days after it receives that notification to issue a notice of proposed rulemaking to amend the Commission's mandatory ATV standard "to include any such revision that the Commission determines is reasonably related to the safe performance of [ATVs] and notify the Institute of any provision it has determined not to be so related." 15 U.S.C. 2089(b)(1) and (2). Thereafter, the Commission has 180 days after publication of the proposed amendment to publish a final amendment to revise the ATV standard. *Id.*

II. Evaluation of ANSI/SVIA 1-2017

ANSI/SVIA 1-2017 contains requirements and test methods relating to ATVs, including vehicle equipment and configuration, vehicle speed capability, brake performance, pitch stability, electromagnetic compatibility, and sound level limits. The Commission reviewed the 2017 edition of the ANSI/SVIA standard and compared it with the 2010 edition, which is currently the mandated consumer product safety standard for ATVs. The Commission considers the following revisions to be material changes:

- Requirements for stop lamps or combination tail-stop lamps on all categories of ATVs;
- Requirements for reflectors for all categories of ATVs.

The standard provides that it will take effect "beginning with 2019 model year vehicles." As explained below, the Commission believes that these revisions are reasonably related to the safe performance of ATVs.

A. Stop Lamps and Reflectors

ANSI/SVIA 1-2017 Section 4.17, Lighting & Reflective Equipment, states that all ATVs shall be equipped with lighting and reflective devices.

1. Stop Lamps

ANSI/SVIA 1-2017 requires stop lamps or combination tail-stop lamps on all adult and transition category ATVs. In May 2015, CPSC requested that SVIA consider adding requirements relating to stop lamps to increase the detectability of ATVs. CPSC staff reviewed 1 year (2007) of ATV-related fatality data involving two ATVs colliding, and

identified 13 rear-end collisions. Of the 13 incidents, eight involved a leading ATV slowing or stopping and a following ATV colliding with the leading vehicle. Although this is only a preliminary analysis, the data illustrate a hazard pattern of rear-end collisions related to braking. CPSC staff subsequently worked with SVIA to develop the stop lamp requirements contained in ANSI/SVIA 1-2017. The Commission believes that adding stop lamp requirements in ANSI/SVIA 1-2017 improves the optional provision in the 2010 edition of the voluntary standard, and that this addition may reduce rear-end collisions related to non-detection of a vehicle braking.

2. Reflectors

ANSI/SVIA 1-2017 requires one amber reflector on each side of the ATV (mounted as far forward as practicable), one red reflector on each side of the ATV (mounted as far rearward as practicable), one red reflector on the rear of the vehicle, and one white reflector on the front of the ATV, if not equipped with a headlamp or conspicuity light. These requirements are for all categories of ATV. In May 2015, CPSC requested that SVIA consider adding requirements relating to reflectors, and worked with SVIA in developing the reflector requirements contained in ANSI/SVIA 1-2017.

Reflector use may increase the detectability of ATVs. CPSC staff's preliminary review of 331 fatal ATV-related vehicular collision incidents found that more than 30 percent of these incidents occurred at night and an additional 5 percent occurred in low light (*i.e.*, dusk). Although many factors contribute to incidents, increasing the visibility of ATVs at night will raise the likelihood that the driver of an oncoming vehicle will detect the ATV. Early detection of an ATV may allow the driver of an oncoming vehicle sufficient time to react and avoid a collision.

Because fatalities occur when ATVs cross public roads between fields or trails, CPSC believes that the requirement for side reflectors is crucial to any new efforts to increase vehicle visibility. The Commission believes that the ANSI/SVIA 1-2017 reflector requirements improve the 2010 edition of the voluntary standard (which lacked a reflector requirement), and that requirements for reflectors to increase the visibility of an ATV at night may reduce vehicular collisions related to non-detection of other vehicles.

III. Effective Date

The CPSIA provides a timetable for the Commission to issue a notice of proposed rulemaking (within 120 days of receiving notification of a revised ANSI/SVIA standard) and to issue a final rule (within 180 days of publication of the proposed rule), but it does not set an effective date. Since issuing the ATV standard in 2009, the Commission has revised it once, in accordance with the revision procedures set out in the CPSIA. Based on comments to the NPR from several ATV companies, the final rule amending the Commission's ATV standard to reference the 2010 edition of the ANSI/SVIA standard provided for an effective date of 60 days from publication of the final rule.

Data from CPSC's ATV Special Study show that 97 percent of consumers who reported that their vehicle had a tail lamp, also claimed that the vehicle had a stop lamp. This suggests that adding stop lamps to ATVs to meet the new ANSI/SVIA 1–2017 requirements will require minimal changes to current production. Additionally, reflectors are a low-technology product that can be obtained in bulk as sheets or rolls of tape. Attaching reflectors in the correct positions on ATVs does not require test and evaluation effort. This suggests that adding reflectors to ATVs to meet the new ANSI/SVIA 1–2017 requirements will require minimal design and labor changes. CPSC believes that the revisions to the 2010 edition of the voluntary standard will not require significant vehicle design and testing, and that a 60-day effective date for this proposed rule will allow companies sufficient time to update their certification labels. Thus, the Commission proposes that the rule would take effect 60 days after publication of a final rule in the **Federal Register**, and it would apply to ATVs manufactured or imported on or after that date.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires that agencies review a proposed rule for the rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency publishes an NPR. 5 U.S.C. 603. Section 605 of the RFA provides that an IRFA is not required if the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial

number of small entities. As explained in this section, the Commission certifies that ANSI/SVIA standard, if promulgated as a final rule, will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b).

The proposed rule would revise the mandatory ATV standard to incorporate the revisions in the 2017 edition of the ANSI/SVIA standard. The most significant changes involve requirements for brake-actuated stop lamps and reflectors. CPSC believes that the vast majority of ATVs already comply with these requirements. Consequently, the Commission anticipates that the cost of the changes required to bring ATVs that do not comply into compliance with the rule will be very low on a per-unit basis. Furthermore, other changes to the standard either increase the options for manufacturers in designing and equipping their vehicles, or are minor changes that clarify—but do not change—the standard's requirement. For these reasons, the Commission certifies that the proposed rule will not have a significant impact on a substantial number of small entities.

V. The Proposed Rule

The proposed rule would revise § 1420.3, "Requirements for four-wheel ATVs." The current rule refers to the ANSI/SVIA 1–2010 standard; the proposed rule would replace this reference with the ANSI/SVIA 1–2017 edition of the standard.

VI. Paperwork Reduction Act

This proposed amendment would not impose any information collection requirements. Accordingly, this rule is not subject to the Paperwork Reduction Act, 44 U.S.C. 3501–3520.

VII. Environmental Considerations

The Commission's regulations provide a categorical exemption for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement as they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This proposed amendment falls within the categorical exemption.

VIII. Incorporation by Reference

The Commission proposes to incorporate by reference ANSI/SVIA 1–2017. The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. For a proposed rule, agencies must discuss in the preamble to the NPR ways that the materials the agency

proposes to incorporate by reference are reasonably available to interested persons or how the agency worked to make the materials reasonably available. In addition, the preamble to the proposed rule must summarize the material. 1 CFR 51.5(a).

In accordance with the OFR's requirements, section II of this preamble summarizes the provisions of ANSI/SVIA 1–2017 that the Commission proposes to incorporate by reference. ANSI/SVIA 1–2017 is copyrighted. Interested persons may purchase a copy of ANSI/SVIA 1–2017 from Specialty Vehicle Institute of America, 2 Jenner, Suite 150, Irvine, CA 92618–3806; telephone: 949–727–3727 ext. 3023; www.svia.org. One may also inspect a copy at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone: 301–504–7923.

IX. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 232(a)(1) of the CPSIA refers to the rules to be issued under that section as "consumer product safety standards." Therefore, the preemption provision of section 26(a) of the CPSA would apply to a rule issued under section 232 of the CPSIA.

X. Notice of Requirements

The CPSA establishes certain requirements for product certification and testing. Certification of children's products subject to a children's product safety rule must be based on testing conducted by a CPSC-accepted third-party conformity assessment body. 15 U.S.C. 2063(a)(2). The Commission is required to publish a notice of requirements (NOR) for the accreditation of third-party conformity assessment bodies to assess conformity with a children's product safety rule to which a children's product is subject. *Id.* 2063(a)(3). On August 27, 2010, the Commission published an NOR for accreditation of third-party conformity

assessment bodies for testing ATVs designed or intended primarily for children 12 years of age or younger. 75 FR 52616. Because the revisions to the 2010 edition of the ANSI/SVIA standard would not substantially alter third-party conformance testing requirements for ATVs designed or intended primarily for children 12 years of age or younger, the current NOR for third-party testing of youth ATVs will remain unchanged. Thus, the Commission considers the existing accreditations that the Commission has accepted for testing to the ATV standard also cover testing to the revised ATV standard.

XI. Request for Comments

This NPR begins a rulemaking proceeding under section 232 of the CPSIA to amend the Commission's mandatory ATV standard to reference the 2017 edition of the ANSI/SVIA standard. We invite all interested persons to submit comments on any aspect of this proposal. During the comment period, ANSI/SVIA 1–2017, *American National Standard for Four-Wheel All-Terrain Vehicles Equipment Configuration, and Performance Requirements*, is available for inspection at the CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923. Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

List of Subjects in 16 CFR Part 1420

Consumer protection, Imports, Incorporation by reference, Infants and children, Information, Labeling, Law enforcement, Recreation and recreation areas, Reporting and recordkeeping requirements, Safety.

For the reasons stated in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations, as follows:

PART 1420—REQUIREMENTS FOR ALL-TERRAIN VEHICLES

■ 1. The authority citation for part 1420 continues to read as follows:

Authority: The Consumer Product Safety Improvement Act of 2008, Pub. Law 110–314, § 232, 122 Stat. 3016 (August 14, 2008).

■ 2. In the second sentence of § 1420.1, remove the words, “April 30, 2012,” and add in their place “(date 60 days after publication of a final rule in the **Federal Register**).”

■ 3. Revise § 1420.3 to read as follows:

§ 1420.3 Requirements for four-wheel ATVs.

Each ATV shall comply with all applicable provisions of the American National Standard for Four-Wheel All-Terrain Vehicles (American National Standards Institute, Inc. ANSI/SVIA 1–2017), approved on June 8, 2017. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from Specialty Vehicle Institute of America, 2 Jenner, Suite 150, Irvine, CA 92618–3806; telephone: 949–727–3727 ext.3023; www.svia.org. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone: 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Alberta E. Mills,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2017–19341 Filed 9–12–17; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA–2011–N–0921]

RIN 0910–ZA50

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to extend, for covered produce other than sprouts, the dates for compliance with the agricultural water provisions in the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption rule. We are proposing to extend the compliance dates to address questions about the practical implementation of compliance with certain provisions and to consider how we might further reduce the regulatory burden or increase flexibility while

continuing to achieve our regulatory objectives, in keeping with the Administration's policies.

DATES: Submit either electronic or written comments on this proposed rule by November 13, 2017.

ADDRESSES: You may submit comments on the extension of the compliance period as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 13, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 13, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and